

# Response to a Commission Proposal for a Regulation on Nutrition and Health Claims (COM(2003) 424 final - 2003/0165 (COD))

October 2003

#### Introduction

The European Heart Network (EHN) has long called for the better regulation of health and nutrition claims. EHN therefore welcomes the Commission's proposal for a Regulation, in particular the restriction of claims to foods that have a specific nutrient profile, and emphasises the need for evidence-based risk reduction claims.

In its 2001 paper 'Nutrition and Health Claims: a European Heart Network Position Paper', EHN stated that the paramount principle in EU policy on nutrition and health claims should be the protection and promotion of public health. EHN recommends that there should be a coherent and comprehensive nutrition policy for the EU. The main purpose of such a policy would be the promotion of public health. It would include prioritised and quantified population dietary goals for foods and nutrients such as those agreed by the European Commission funded Eurodiet Project<sup>1</sup>. EHN has argued that such a policy would create a framework for initiatives such as the development of a Regulation on nutrition and health claims<sup>2</sup>.

EHN considers that the Commission's proposal for a Regulation on nutrition and health claims does not consider the promotion of public health sufficiently. EHN makes the following suggestions to the draft Regulation which it believes would improve it.

#### 1. Article 1 - Subject matter and scope

#### Recommendation:

Change article 1.1 to: 'This Regulation is intended to harmonise the provisions laid down by law, regulation or administrative action in Member States which relate to nutrition and health claims in order to ensure the effective functioning of the internal market whilst providing a high level of <u>public health</u> and consumer protection.'

<sup>&</sup>lt;sup>1</sup> Eurodiet (2001) Eurodiet core report. Nutrition and diet for healthy lifestyles in Europe: Science and policy implications. Public Health Nutrition 4(2A) 265-73.

<sup>&</sup>lt;sup>2</sup> European Heart Network (2002) Food, Nutrition and Cardiovascular Disease Prevention in the European Region: Challenges for the New Millennium. EHN: Brussels.

#### Rationale:

EHN believes that the paramount principle in EU policy on nutrition and health claims should be the protection and promotion of public health.

#### 2. Article 2 - Definitions

#### Recommendation:

Change the definition of a reduction of a disease risk claim to: 'reduction of a disease risk claim means any health claim that states suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces the risk of a human disease.'

#### Rationale:

EHN notes that some food categories, foods and nutrients have been shown to reduce the risk of diseases without necessarily reducing known risk factors for diseases. For example the mechanism by which an increased consumption of fruit and vegetables reduces the risk of cardiovascular diseases (CVD) or cancer is not entirely certain. EHN, therefore, sees no reason for the words 'a risk factor in the development of' in the Commission's proposed definition.

### 3. Article 3 - General principles for all claims

#### Recommendations:

(i) Add new sub-paragraph to second paragraph: '(...the use of nutrition and health claims shall not:) e) undermine the protection or promotion of public health'.

#### Rationale:

EHN considers that there is a danger that the Regulation as currently proposed would allow an increasing number of claims relating to relatively unimportant health issues compared to major health burdens such as CVD and cancer and an opportunity to use claims for the benefit of public health will be lost, particularly in view of the fact that the Regulation will permit the use of disease risk reduction claims which have hitherto been prohibited. Accordingly EHN recommends that claims should only be allowed if they do not undermine the protection and promotion of public health.

#### 4. Article 4 - Restriction on the use of nutrition and health claims

## Recommendation:

- (i) In Article 4.1 (b) add 'added' before 'sugars'
- (ii) Add 'health bodies' before 'and consumer groups' in the sentence which reads: 'In setting the nutritional profiles, the Commission shall seek the advice of the Authority and carry out consultations with interested parties, in particular food business operators and consumer groups'

#### Rationale:

Added (or free sugars) are the major concern of expert bodies who have examined the relationship between diet and health. See for example the recent report of the Joint WHO/FAO Expert Consultation on diet, nutrition and the prevention of chronic diseases<sup>3</sup>. Accordingly we recommend that nutrient profiles should include criteria for added or free sugars rather than all sugars.

Supporting all of Article 4, EHN is particularly pleased with the inclusion of Article 4.1 and feels that this article will give consumers a high level of protection against misleading claims and help to promote public health. EHN suggests that health bodies should also be consulted when developing the nutrient profiles.

#### 5. Article 6 - Scientific substantiation for claims

#### Recommendation:

Replace Paragraph 1 'Nutrition and health claims shall be based on and substantiated by generally accepted scientific data.' with: 'Nutrition and health claims shall be based on <u>a</u> systematic review of all the available scientific evidence relating to the validity of the claim.'

#### Rationale:

Paragraph 1 in its current form suggests that any amount of 'generally accepted scientific data' would be sufficient to substantiate a claim. For all health and nutrition claims there will be some accepted data which support the claim and some which do not. It is essential that all the available scientific evidence relating to the claim is reviewed before a claim can be said to be substantiated.

EHN also notes that claims cannot be based on or substantiated by data alone. There has, at some point, to be a collection, synthesis and interpretation of data i.e. a review. EHN notes that there are now well-established methods for carrying out reviews of scientific data. Systematic reviews seek to ensure that all relevant data are considered and that only data of adequate quality are used to draw conclusions. Systematic reviews are also carried out according to defined protocols to ensure that they can be reproduced and updated when new data becomes available.

## 6. Chapter III - Nutrition Claims

#### Recommendation:

Re-title to: Nutrition Claims and Claims for Other Substances that Have a Nutritional or Physiological Effect.

#### Rationale:

EHN notes that it would seem to be the intention of the Commission that the Regulation should cover claims for substances other than nutrients which have a nutritional or

<sup>&</sup>lt;sup>3</sup> World Health Organisation (2003) Diet, Nutrition and the Prevention of Chronic Diseases. WHO Technical Report Series 916.

physiological effect (see in particular Recital (5)). EHN agrees that the Regulation should do so.

Accordingly EHN recommends that Chapter III and the associated Annex, as well as covering nutrition claims, should cover claims for other substances having a nutritional or physiological effect. EHN considers, for example, that Chapter III should cover a claim such as 'containing one portion of fruit and vegetables per serving'. Such a claim, if it could be substantiated, would be useful to consumers seeking to adopt a healthy diet, but should be subject to the same restrictions as nutrition claims.

## 7. Article 11 - Implied Health Claims

#### Recommendation:

Delete Article 11 in its entirety

#### Rationale:

EHN considers that if a claim is evidence-based, true and helps promote public health then it should be allowed. EHN considers that this article would prohibit the use of some claims that are both true and would help promote public health.

In particular Article 11.1(a) would seem to prohibit some useful schemes – such as the green key hole scheme established by the Swedish National Food Administration<sup>4</sup> – which aim to signal to consumers which foods – based on their nutrition profiles – are more likely to contribute to a generally healthier diet. EHN considers that healthy diets promote overall good health and well being (and do not just reduce the risk of specific disease) and claims should be allowed to refer to that fact.

Similarly Article 11.1(d) could prohibit some useful schemes run by health charities, such as heart foundations, which aim to signal to consumers which foods might help to reduce the risk of particular diseases.

EHN acknowledges that there would seem to be frequent cases of foods or supplements making claims for psychological and behavioural functions or for slimming or weight control which are unfounded. Nevertheless, EHN considers that if such claims could be substantiated and help promote public health, then they should be allowed.

## 8. Article 12 - Health claims describing a generally accepted role of a nutrient or other substance

#### Recommendation:

Change the title of this article to: 'Health claims describing a generally accepted <u>and well</u> <u>established</u> role of a nutrient or other substance.' Likewise, change the first paragraph of this article to: 'By way of derogation from Article 10 (1), health claims describing the role of a nutrient or of another substance in growth, development and the normal functions of the body, which are based on generally accepted <u>and well established</u> scientific data ....'

<sup>&</sup>lt;sup>4</sup> Larsson I et al (1999) Eur J Clin Nutr 33: 776-80 (discussed in A systematic review of the research on consumer understanding of nutrition claims (2003). EHN: Brussels)

#### Rationale

Please refer to comments made to Article 6.

#### 9. Annex

#### Recommendation:

Add criteria for claims for polyunsaturated fat, including claims for n-6 polyunsaturated fat and n-3 polyunsaturated fat, trans fat, carbohydrate, fruit and vegetables.

#### Rationale:

EHN recommends that nutrition claims on foods for general consumption should be made where there are agreed population dietary goals such as those agreed by the European Commission funded Eurodiet Project <sup>5</sup>. Accordingly EHN recommends that the Annex should include criteria for making claims for polyunsaturated fat, including claims for n-6 polyunsaturated fat and n-3 polyunsaturated fat, trans fat, carbohydrate and fruit and vegetables.

EHN suggests that where there is no agreed population goal, then nutrition claims should not be made on a food for general consumption. EHN considers that claims for other nutrients should be restricted to nutrients covered by Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foods for particular nutrition uses <sup>6</sup>.

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<sup>&</sup>lt;sup>5</sup> Eurodiet (2001) Eurodiet core report. Nutrition and diet for healthy lifestyles in Europe : Science and policy implications. Public Health Nutrition 4(2A) 265-73.

<sup>&</sup>lt;sup>6</sup> Council Directive 89/398/EEC of 3 May 1989, published in the Official Journal L 186 of 30 June 1989 P. 0027 - 0032